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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.       |
|--|-------------|----------------------|---------------------------------|------------------------|
| 10/826,960   | 04/15/2004  | Sheng-Ping Zhong     | 10527-447001 / 02-200           | 2208                   |
| 26191 7590 02/04/2008<br>FISH & RICHARDSON P.C.<br>PO BOX 1022<br>MINNEAPOLIS, MN 55440-1022 |             |                      | EXAMINER<br>ROZANSKI, MICHAEL T |                        |
|  |             |                      | ART UNIT<br>3768                | PAPER NUMBER           |
|  |             |                      | MAIL DATE<br>02/04/2008         | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/826,960

Applicant(s)

ZHONG ET AL.

Examiner

Michael Rozanski

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-47, 54 and 55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-47, 54 and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 54 and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Pacetti (US 6,574,497).

***Claims 54 and 55:*** Pacetti discloses generating an MR image of a medical device, such as a guidewire, guide catheter, endovascular graft, biopsy needle, stent, or inflatable balloon catheter, and proximate body tissue, wherein the device has incorporated therein an imaging material comprising selected MRI detectable nuclei, such as hydrogen, phosphor, fluorine, or sodium nuclei (col. 2, lines 12-24; col. 6, lines 13-37; col. 6, line 65-col. 7, line 5; col. 9, lines 26-44). MRI images are taken including at least a portion of the medical device, which comprises a first image data, and including MRI detectable nuclei contained in the imaging material, which comprises a second image data, and are combined and displayed (col. 7, lines 8-29; col. 8, lines 4-37).

The MRI scanner is able to transmit excitation pulses for two processes at either the same or different frequencies, a distinct magnetic field strength can be used for each process, and the processes can be performed at the same or different times (col. 7, line 30-col. 8, line 3). The imaging material is a liquid, such as an emulsion, and is encapsulated in a microsphere or into the wall of the microporous polymer material of the medical device containing structural material, which can be coated with fluorine-19 imaging material (col. 8, line 56-col. 9, line 25; col. 10, lines 21-35; col. 11, lines 24-39). The coating can comprise a network of polymer chains (col. 11, lines 40-49). Imaging material also comprises a spin  $\frac{1}{2}$  nucleus or at least two spin  $\frac{1}{2}$  nuclei that are magnetically equivalent (col. 3, lines 40-52). Furthermore, the device comprises a relaxation agent that decreases the spin-lattice relaxation time of the nuclei contained in the medical device (col. 2, lines 25-42).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-9, 14-23, 25-32, and 34-47 rejected under 35 U.S.C. 102(e) as being unpatentable over ***Pacetti*** in view of ***Chui*** (US Pub 2002/0101241).

**Claims 1-3, 5-9, 14-23, 25-32, and 34-47:** Pacetti discloses generating an MR image of a medical device, such as a guidewire, guide catheter, endovascular graft, biopsy needle, stent, or inflatable balloon catheter, and proximate body tissue, wherein the device has incorporated therein an imaging material comprising selected MRI detectable nuclei, such as hydrogen, phosphor, fluorine, or sodium nuclei (col. 2, lines 12-24; col. 6, lines 13-37; col. 6, line 65-col. 7, line 5; col. 9, lines 26-44). MRI images are taken including at least a portion of the medical device, which comprises a first image data, and including MRI detectable nuclei contained in the imaging material, which comprises a second image data, and are combined and displayed (col. 7, lines 8-29; col. 8, lines 4-37).

The MRI scanner is able to transmit excitation pulses for two processes at either the same or different frequencies, a distinct magnetic field strength can be used for each process, and the processes can be performed at the same or different times (col. 7, line 30-col. 8, line 3). The imaging material is a liquid, such as an emulsion, and is encapsulated in a microsphere or into the wall of the microporous polymer material of the medical device containing structural material, which can be coated with fluorine-19 imaging material (col. 8, line 56-col. 9, line 25; col. 10, lines 21-35; col. 11, lines 24-39). The coating can comprise a network of polymer chains (col. 11, lines 40-49). Imaging material also comprises a spin  $\frac{1}{2}$  nucleus or at least two spin  $\frac{1}{2}$  nuclei that are magnetically equivalent (col. 3, lines 40-52). Furthermore, the device comprises a relaxation agent that decreases the spin-lattice relaxation time of the nuclei contained in the medical device (col. 2, lines 25-42).

In regard to claim 1, Pacetti substantially discloses all features of the current invention but does not specifically disclose a receiver coil of a medical device. In the same field of endeavor, Chui teaches of a medical device with an RF internal receiving coil that is used to provide magnetic resonance imaging enhancement (see Abstract). It would have been obvious to one with ordinary skill in the art at the time the invention was made to have incorporated the teaching of Chui in order to enhance MR imaging.

**Claims 4 and 10-13:** Pacetti disclose using selected MRI detectable nuclei such as hydrogen and sodium, but do not specifically disclose using phosphor or iodine nuclei. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have incorporated such nuclei in order to permit improved MR imaging of a selected medical device and proximate body tissue under different conditions.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Pacetti and Chui** as applied to claim 30 in further view of **Young et al** (US 5,817,017).

**Claim 33:** Pacetti and Chui substantially discloses all features of the current invention but does not specifically disclose microporous material comprising a film or a foam. In the same field of endeavor, Young et al teach such a film (col. 8, lines 40-59). It would have been obvious to one with ordinary skill in the art at the time the invention was made to have incorporated the teaching of Young et al in order to enable a liquid to be encapsulated therein.

***Response to Arguments***

Applicant's arguments filed 11/12/07 have been fully considered but they are not persuasive. In regard to claim 1, Applicant has cancelled claim 48 and placed the limitation into claim 1. Applicant argues that it would not have been obvious to combine Chui with Pacetti because Pacetti teach a passive system that involves no wires, circuits, connections, or moving parts. However, Examiner finds that although Pacetti uses a passive system, it is also noted that it is unknown whether an active or passive tracking strategy would be deemed better by research (col 7, lines 8-11). Chui is used to modify the Pacetti system whereby a receiving coil enhances the MRI signal at a point of interest. Pacetti fully contemplates that passive or active strategies may be used for tracking and, therefore, that the teachings can be combined.

In regard to claim 54, Applicant argues that Pacetti do not excite nuclei with the same frequency using different magnetic field strengths. The passage that Applicant cites (col 7, lines 64-66) refer to differing resonant frequencies, not the excitation frequencies. However, all nuclei have resonant frequencies that are directly proportional to the strength of the magnetic field applied. The nuclei taught by Pacetti have the same spin behavior but have different resonant frequencies as disclosed when different field strength is applied under the same excitation frequency.

In regard to claim 55, Applicant argues that Pacetti do not disclose perfluoro-15-crown-5-ether. However, Examiner finds that Pacetti teach of medical devices incorporating compounds which contain fluorine-19 (col 6, lines 13-24). Such a compound is perfluoro-15-crown-5-ether and, therefore, Pacetti meets the limitation by

teaching a broad group of compounds that encompass the specifically claimed compound.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Rozanski whose telephone number is 571-272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
MR

 ERIC F. WINAKUR  
PRIMARY EXAMINER